

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)REC'D 14 DEC 2004
WIPO PCT

Applicant's or agent's file reference P10615 PC/P10240	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA416)	
International application No. PCT/DK 03/00555	International filing date (day/month/year) 25.08.2003	Priority date (day/month/year) 23.08.2002
International Patent Classification (IPC) or both national classification and IPC C07K14/47		
Applicant COPENHAGEN BIOTECH ASSETS APS et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 23.03.2004	Date of completion of this report 14.12.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Masturzo, P Telephone No. +31 70 340-2275



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/DK 03/00555**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-49 as originally filed

Sequence listings part of the description, Pages

1-18 as originally filed

Claims, Numbers

1-86 as originally filed

Drawings, Sheets

1/9-9/9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-86
	No: Claims	
Inventive step (IS)	Yes: Claims	50-53
	No: Claims	1-49, 54-86
Industrial applicability (IA)	Yes: Claims	1-84
	No: Claims	85-86

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: Protein Engineering (06-2002), 15(6), 529-537;
D2: WO-A-9531466;
D3: WO-A-9710505;
D4: WO-A-9915640;
D5: WO-A-9704814;
D6: WO-A-9746572.

1) D1 discloses (see e. g. Figure 1) conjugates falling into the wording of claim 1 and endowed with pertinent scope. Similar conjugates are disclosed in D2 (see e. g. claim 4) and their uses are further described in D3-D5. D6 discloses still other conjugates falling in the wording of claim 1, where the FLAG sequence has been inserted within the sequence of the PrP protein (see e. g. page 29). Though these conjugates disclose prion-protein derived sequences linked with other sequences (marker or else), they do not have a "non-linear" character as disclosed in claim 1 and therefore claims 1-86 are new under Art. 33(2) PCT.

2) If the previously cited documents are considered to represent the most relevant prior art for the claims 1-86 of the present application, the objective problem can only be set as providing alternative composite prion conjugates. The applicant has provided a very scant number of examples and no comparative tests. This would imply that the definition of the objective problem cannot be any else than the above. This leads the skilled person to ask himself how he could reach the necessary condition set out in claim 1, i. e. the mimicry between these constructs and PrPSc-specific epitopes. As the indication to fulfill this condition are altogether lacking, this condition assumes the value of a result to be achieved and therefore not admissible. On the basis of the above the presence of an inventive step under Art. 33(3) PCT to claims 16-17, 22-23, 31-49, 54-64 for plausibility reasons cannot be granted. To this objection it should be added that claims 1-8, 18-21, 24-30 and 65-86 have now become lacking in inventive step under Art. 33(3) PCT because they also are distinguished by a desideratum feature. Claims 50-53, referring to examples which have not been anticipated or fairly suggested individually, are considered as inventive under Art. 33(3) PCT.

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3) For the assessment of the present claims 85-86 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment. The remaining claims 1-84 are endowed with industrial applicability under Art. 33(4) EPC.